REMARKS

Reconsideration of the application is respectfully requested. Claims 13-16, 22-26, 31-36, 50-53, 59-62, 68-73, 87-90, 96-99, 105-110, 112-127, 131-137, 139-150, 152-163, 165-176, and 178-195 are pending and at issue.

Obviousness-type Double Patenting Rejection

Claims 13-16, 22-26, 31-36, 50-53, 59-62, 68-73, 87-90, 96-99, 105-110, 112-127, 131-137, 139-150, 152-163, 165-176, and 178-195 stand rejected under the judicially created doctrine of obviousness-type double patenting over various claims of U.S. Patent Nos. 6,071,538; 5,714,167; 6,348,207; 6,221,367; 6,916,489; 7,005,141; 6,461,643; and 5,629,020. (The June 22, 2007 Office Action appears to erroneously refer to U.S. Patent No. 5,629,090 (the '090 Patent) rather than U.S. Patent No. 5,629,020 (the '020 Patent). The Examiner refers to claims 25-29 of the patent. The '090 Patent only has 11 claims, does not have a common inventor or assignee with the present application, and is directed to different technology (starch hydrolysates). In contrast, the '020 Patent has the same assignee as the present application.)

Applicants respectfully disagree with the Examiner. However, in order to expedite prosecution of this application, upon the finding of allowable subject matter, applicants will file a terminal disclaimer to overcome these rejections.

Obviousness Rejection

Claims 13-16, 22-26, 31-36, 50-53, 59-62, 68-73, 87-90, 96-99, 105-110, and 112-127, 131-137, 139-150, 152-163, 165-176, and 178-195 stand rejected as obvious over Brown (U.S. Patent No. 4,826,817) alone or over Morishita (U.S. Patent No. 4,873,087) in view of Brown.

Brown teaches a conjugate in which a therapeutic compound to be delivered is covalently bound to an amino acid and hydroxy amino acid transporter:

> a new approach is made utilizing an amino acid or hydroxyamino acid as a transporter for known therapeutic agents, linking the amino acid or hydroxyamino acid to the therapeutic agent by way of an ester linkage between the amino acid or hydroxyamino acid molecule and the molecule of the therapeutic agent. ...

(col. 1, lines 53-59, underlining added). Brown explains that after crossing biological barriers, the ester linkage is destroyed generating *in vivo* the free amino acid or hydroxyamino acid and the therapeutic compound:

> The amino acid or hydroxyamino acid acts as a carrier for the therapeutic compound, in transport of the compound across biological barriers, including cell membranes and the blood brain barrier. After passage of the barrier, the new compound enters the metabolic system of the animal, where the ester linkage is destroyed by naturally-occurring esterases present in the animal, thus regenerating free amino acid or hydroxyamino acid and the known therapeutic compound.

(col. 1, line 62, to col. 2, line 3).

The pending claims specify that the perturbant and the biologically active agent are non-covalently complexed.in the supramolecular complex. The ester linkage in Brown connecting the amino acid or hydroxy amino acid to the therapeutic compound is a covalent linkage. Brown neither discloses nor suggests administration of a supramolecular complex in which the perturbant and the biologically active agent are non-covalently complexed as presently claimed. Therefore, Brown does not establish a *prima facie* case of obviousness of the present claims.

The Examiner contends that it would have been obvious to use the amino acids or derivatives of Brown or Morishita "as carriers for delivering therapeutic agents via subcutaneous, intranasal or sublingual routes because Morishita recognizes that the compounds are effective for delivery via mucosal membranes and Brown teaches that the compounds are effective for any or all

routes including subcutaneous." *See* page 5 of the June 22, 2007 Office Action. The Examiner's contention presumes that the compounds in Brown and Morishita are the same - they are not. Morishita describes administration of a "medicine simultaneously with ... an absorption promoter" (Morishita, col. 1, lines 5-13). The medicine and absorption promoter in Morishita are not covalently bound together as in Brown. For instance, example 5 of Morishita (col. 8, lines 22-50) describes a preparation in which the medicine cephalothin sodium and an absorption promoter were each pulverized, dispersed in water, and added to a fatty base (Witepsol H-15). While Morishita discloses a mixture containing a medicine and an absorption promoter where the two are not covalently bound, Brown discloses a single compound in which an amino acid is covalently bound to a therapeutic compound. Because the "compounds" in Brown and Morishita are different, a skilled artisan would not have been motivated to apply the teachings of Brown regarding routes of administration to Morishita.

For the foregoing reasons, Brown alone or in combination with Morishita does not render obvious the presently claimed methods, and applicants respectfully request withdrawal of this rejection.

CONCLUSION

In view of the above remarks, applicants respectfully request the withdrawal of all rejections and the allowance of all pending claims.

If there are any remaining issues that the Examiner believes could be resolved through either a Supplemental Response or an Examiner's Amendment, the Examiner is respectfully requested to contact the undersigned at the telephone number indicated below.

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Respectfully submitted,

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